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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,374	07/06/2006	Alexander Dubson	DUBSON3	2997

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EXAMINER	
SHARMA, YASHITA	
ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,374	DUBSON, ALEXANDER	
	Examiner	Art Unit	
	YASHITA SHARMA	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3, 6, 7, 15, 27, 31-34, 40-42, 47, 49, 61-64, 73-46, 84, 115, 120 and 121* is/are pending in the application.

4a) Of the above claim(s) *2,3,7,15,33,40-42,47,49,61-64,73-76,84 and 121* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,27,31,32,34,115 and 120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/06/2006 and 12/26/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/24/2009. Claims 2-3, 7, 15, 33, 40-42, 47, 49, 61-64, 73-76, 84 and 121 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Thus, claims 1, 6, 27, 31, 32, 34, 115 and 120 are presently pending in this application.

2. Applicant's request to withdraw the restriction requirement between Groups I and II has been considered but is not persuasive. Claim 40 is a method of manufacturing a medical device which is a separate statutory category of invention than the medical device in claim 1. Claims 1 and 40 have been previously restricted and remain restricted with claim 1 as the elected invention and claim 40 has being the withdrawn invention. Once claim 1 is found to be allowable, claim 40 will be rejoined with the allowable claims. The Dubson et al. (2004/0030377) reference discloses the special technical feature common to both original claims 1 and 40 since it has an anastomotic member or stent and coatings of electrospun fibers (claims 1, 15 and 16; abstract) , therefore the two different inventions lack a unity of invention and are restrictable since their special technical feature has been found and the novelty has been broken.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 15 and 16 of copending Application No. 10433620. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 15 and 16 of application 10433620 require an anastomotic member or stent having an electrospun non-woven cover or outer coat and electrospun non-woven liner or inner coat.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the electrospun fibers of the non-woven liner *and* non-woven cover are aligned or the electrospun fibers of the non-woven liner *or* non-woven cover are aligned? The claim should be rewritten with either "and" or the "or" limitation.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1, 6, 27, 32 and 34 have been rejected under 35 U.S.C. 102(b) as being anticipated by Dereume et al. (5,948,018).**

9. Regarding claim 1, Dereume discloses a medical device 21 (Fig. 1) for implantation in a vessel, comprising at least one anastomotic member (tubular support, 22) (Fig. 1) at least partially interposing a non-woven liner 24 (Fig. 1) of electrospun fibers and a non-woven cover 23 (Fig. 1) of electrospun fibers (col. 4, lin. 29-31); the at least one anastomotic member being designed for engaging at least one end of the medical device to a wall of the vessel upon implantation of the medical device within the vessel (col. 5, lin. 25-30).

10. Regarding claim 6, Dereume discloses at least one anastomotic member (tubular support, 22) (Fig. 1) comprises a plurality of hooks (staples, 36) (Fig. 3) for connecting the device to the wall of the vessel (col. 6, lin. 41-48).

11. Regarding claim 27, Dereume discloses at least one adhesive layer (col. 5, lin. 5-10) for adhering at least two of: the non-woven liner, the non-woven cover and the at least one anastomotic member (col. 4, lin. 64-67).

12. Regarding claim 32, as best understood, Dereume discloses the electrospun fibers of the non-woven liner and/or the non-woven cover are randomly aligned (col. 4, lin. 36-43).

13. Regarding claim 34, Dereume discloses wherein at least one of the non-woven liner and the non-woven cover comprises at least one medicament incorporated therein,

for delivery of the at least one medicament into a body vasculature during or after implantation of the device within the body vasculature (claim 12 discloses the device surface being coated for biocompatibility and drug delivery).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. **Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. (5,948,018) in view of Bornat (4,323,525).** As best understood, Dereume discloses the claimed invention; except for electrospun fibers of the non-woven liner and/or the non-woven cover are aligned at a predetermined orientation relative to a longitudinal axis of the device. However, Bornat teaches a similar device comprising electrospun fibers aligned at a predetermined orientation relative to a longitudinal axis of the device (the electrospun fibers are annularly oriented perpendicular to the longitudinal axis of the device, as best shown in Figs. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the liner and/or cover in Dereume to include electrospun fibers aligned at a predetermined orientation relative to a longitudinal axis of the device, for the purpose of enhancing the surface bonding of the fibers relative to each other and the device surface.

16. **Claims 115 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. (5,948,018) in view of Goldsteen et al. (5,976,178) further in view of Hogendijk (6,080,175).**

17. Regarding claim 115, Dereume discloses the claimed invention; except for a kit comprising an accessory device for forming an opening in the wall of the vessel, the accessory device comprising a tubular encapsulation designed and constructed for receiving the medical device, a cutting member integrated with or attached to an end of the tubular encapsulation and capable of forming an opening in the wall of the vessel, and a vacuum channel for channeling efflux of biological material from the tubular encapsulation. However, Goldsteen teaches a similar invention comprising an accessory device (Fig. 33) comprising a tubular encapsulation 440' (Fig. 33) designed and constructed for receiving the medical device (graft, 430) (Fig. 34), a cutting member (tip 412') (Fig. 33) integrated with or attached to an end of the tubular encapsulation (as shown in Fig. 33, the tip 412' is integrated with the tubular encapsulation at threads 442 and 444) and capable of forming an opening in the wall of the vessel (col. 16, lin. 44-47). Furthermore, Hogendijk teaches a vacuum channel 52 (Fig. 2A) for channeling efflux of biological material from the tubular encapsulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Dereume to include an accessory device for forming an opening in the wall of the vessel, the accessory device comprising a tubular encapsulation designed and constructed for receiving the medical device, a cutting member integrated with or attached to an end of the tubular encapsulation and capable of forming an

opening in the wall of the vessel, and a vacuum channel for channeling efflux of biological material from the tubular encapsulation, for the purpose of allowing an easier access to the implantation site without requiring a surgical procedure and furthermore to prevent any release of debris into the vascular system.

18. Regarding claim 120, Dereume discloses at least one anastomotic member (tubular support, 22) (Fig. 1) comprises a plurality of hooks (staples, 36) (Fig. 3) for connecting the device to the wall of the vessel (col. 6, lin. 41-48).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YASHITA SHARMA whose telephone number is (571)270-5417. The examiner can normally be reached on Monday - Thursday, 8 am to 4 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Y. S./
Examiner, Art Unit 3774
/Thomas J Sweet/
Primary Examiner, Art Unit 3774